

§ 71.105 Quality assurance program.

(a) The licensee shall establish, at the earliest practicable time consistent with the schedule for accomplishing the activities, a quality assurance program that complies with the requirements of §§ 71.101 through 71.137. The licensee shall document the quality assurance program by written procedures or instructions and shall carry out the program in accordance with those procedures throughout the period during which the packaging is used. The licensee shall identify the material and components to be covered by the quality assurance program, the major organizations participating in the program, and the designated functions of these organizations.

(b) The licensee, through its quality assurance program, shall provide control over activities affecting the quality of the identified materials and components to an extent consistent with their importance to safety, and as necessary to assure conformance to the approved design of each individual package used for the shipment of radioactive material. The licensee shall assure that activities affecting quality are accomplished under suitably controlled conditions. Controlled conditions include the use of appropriate equipment; suitable environmental conditions for accomplishing the activity, such as adequate cleanliness; and assurance that all prerequisites for the given activity have been satisfied. The licensee shall take into account the need for special controls, processes, test equipment, tools, and skills to attain the required quality, and the need for verification of quality by inspection and test.

(c) The licensee shall base the requirements and procedures of its quality assurance program on the following considerations concerning the complexity and proposed use of the package and its components:

- (1) The impact of malfunction or failure of the item to safety;
- (2) The design and fabrication complexity or uniqueness of the item;
- (3) The need for special controls and surveillance over processes and equipment;

(4) The degree to which functional compliance can be demonstrated by inspection or test; and

(5) The quality history and degree of standardization of the item.

(d) The licensee shall provide for indoctrination and training of personnel performing activities affecting quality, as necessary to assure that suitable proficiency is achieved and maintained. The licensee shall review the status and adequacy of the quality assurance program at established intervals. Management of other organizations participating in the quality assurance program shall review regularly the status and adequacy of that part of the quality assurance program which they are executing.

§ 71.107 Package design control.

(a) The licensee shall establish measures to assure that applicable regulatory requirements and the package design, as specified in the license for those materials and components to which this section applies, are correctly translated into specifications, drawings, procedures, and instructions. These measures must include provisions to assure that appropriate quality standards are specified and included in design documents and that deviations from standards are controlled. Measures must be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the safety-related functions of the materials, parts, and components of the packaging.

(b) The licensee shall establish measures for the identification and control of design interfaces and for coordination among participating design organizations. These measures must include the establishment of written procedures, among participating design organizations, for the review, approval, release, distribution, and revision of documents involving design interfaces. The design control measures must provide for verifying or checking the adequacy of design, by methods such as design reviews, alternate or simplified calculational methods, or by a suitable testing program. For the verifying or checking process, the licensee shall designate individuals or groups other

than those who were responsible for the original design, but who may be from the same organization. Where a test program is used to verify the adequacy of a specific design feature in lieu of other verifying or checking processes, the licensee shall include suitable qualification testing of a prototype or sample unit under the most adverse design conditions. The licensee shall apply design control measures to items such as the following:

- (1) Criticality physics, radiation shielding, stress, thermal, hydraulic, and accident analyses;
 - (2) Compatibility of materials;
 - (3) Accessibility for inservice inspection, maintenance, and repair;
 - (4) Features to facilitate decontamination; and
 - (5) Delineation of acceptance criteria for inspections and tests.
- (c) The licensee shall subject design changes, including field changes, to design control measures commensurate with those applied to the original design. Changes in the conditions specified in the package approval require NRC approval.

§71.109 Procurement document control.

The licensee shall establish measures to assure that adequate quality is required in the documents for procurement of material, equipment, and services, whether purchased by the licensee or by its contractors or subcontractors. To the extent necessary, the licensee shall require contractors or subcontractors to provide a quality assurance program consistent with the applicable provisions of this part.

§71.111 Instructions, procedures, and drawings.

The licensee shall prescribe activities affecting quality by documented instructions, procedures, or drawings of a type appropriate to the circumstances and shall require that these instructions, procedures, and drawings be followed. The instructions, procedures, and drawings must include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished.

§71.113 Document control.

The licensee shall establish measures to control the issuance of documents such as instructions, procedures, and drawings, including changes, which prescribe all activities affecting quality. These measures must assure that documents, including changes, are reviewed for adequacy, approved for release by authorized personnel, and distributed and used at the location where the prescribed activity is performed. These measures must assure that changes to documents are reviewed and approved.

§71.115 Control of purchased material, equipment, and services.

(a) The licensee shall establish measures to assure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. These measures must include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products on delivery.

(b) The licensee shall have available documentary evidence that material and equipment conform to the procurement specifications before installation or use of the material and equipment. The licensee shall retain, or have available, this documentary evidence for the life of the package to which it applies. The licensee shall assure that the evidence is sufficient to identify the specific requirements met by the purchased material and equipment.

(c) The licensee shall assess the effectiveness of the control of quality by contractors and subcontractors at intervals consistent with the importance, complexity, and quantity of the product or services.

§71.117 Identification and control of materials, parts, and components.

The licensee shall establish measures for the identification and control of materials, parts, and components. These measures must assure that identification of the item is maintained by heat number, part number, or other appropriate means, either on the item or